

Pharmaceutical Supply Chain Initiative (PSCI) Corrective Action Plan Report (CAPR) for PSCI Audit at Supplier

AUDITOR AND AUDIT REPORT INFORMATION

Report Number:	RPH201958		
Date of audit:	05-06 December 2019	Date and type of previous audit:	N/A
Audit Firm Name:	TUV Rheinland (Guangdong) Co., Ltd.		
Lead Auditor Name:	[REDACTED]	Title:	Lead Auditor
Names of other auditors	[REDACTED]	Title:	EHS Auditor
International Phone Number:	[REDACTED]	Email Address:	[REDACTED]

FACILITY DETAILS

Company Name:	[REDACTED]		
Parent Company Name (if applicable)	[REDACTED]		
Street Address:	[REDACTED]		
City:	Shanghai	Site State/Province/County :	Shanghai
Postal/Zip Code:	201203	Site Country:	China

Facility Background Information

Please indicate which of the following best describes this facility (check all that apply):	<input type="checkbox"/> API (Drug substance and intermediates) <input type="checkbox"/> Drug product <input type="checkbox"/> Primary Packaging <input type="checkbox"/> Secondary Packaging, <input type="checkbox"/> Distribution, <input type="checkbox"/> Biological manufacture, <input type="checkbox"/> Chemical <input type="checkbox"/> R&D <input type="checkbox"/> Service provider <input checked="" type="checkbox"/> Other (describe) Contract Research Laboratories
Describe type of work currently being, or proposed to be, performed at this facility, and product type(s):	Small molecule and Large molecule bioanalytical analysis, DMPK

SITE CONTACT INFORMATION

Site Representative Name (host):	[REDACTED]	Title:	General Manager / Executive Vice President
International Phone Number:	[REDACTED]	Email Address:	[REDACTED]

PSCI Supplier Corrective Action Plan Report (CAPR)

Findings, Corrective Actions and Follow-up

Finding Number <i>The reference number of the Finding from the Audit Report</i>	PSCI Principle <i>(e.g. Ethics, Management Systems)</i>	Finding Type (Critical, Other) <i>Please state whether Critical, Other finding</i>	Description of Finding <i>(as done in the PSCI Audit Report)</i>	Agreed Corrective Actions <i>Details of actions to follow up on the Findings</i>	Recommended Completion Timescale <i>Timescale (Immediate, 30, 60, 90, 180, 365 days)</i>	Verification Method <i>Desktop / Follow-Up Visit</i>	Agreed by Management and Name of Responsible Person: <i>Note if management agree to the Finding, and document name of responsible person</i>	Verification Evidence and Comments <i>Details on corrective action evidence</i>	Status <i>Open/Closed or comment</i>
No. 1 Q 3	Management System Legal and Customer Requirements	Other – Minor	The company did not assess ongoing compliance with Health, Safety, and Environment, Business Ethics issues, and Labor regulations. Labor and Ethics regulations are not included in the list of laws and regulations of the company. 企业没有评估是否符合 EHS, 劳工, 商业道德法规。企业的法律法规清单中未包括劳工和商业道德方面的法规。	The company should identify all related law and regulations and assess the effectiveness of the company Health, Safety, and Environment, Business Ethics issues, and Labor practices and programs.	90	Desktop			
No 2. Q 4	Management System Legal and Customer Requirements	Other – Minor	The company did not systematically evaluate its suppliers' practices around Labor, Ethics, Environment, Health & Safety aspect by on-site assessment/audit or desktop assessment (e.g. questionnaires). 企业未能针对供应商 EHS, 劳工, 商业道德部分通过问卷或是现场评审方式进行相关评估。	The company should establish processes to enforce responsible business practices, aligned with the PSCI Principles, with their suppliers, i.e. Labor, Ethics, Environment, Health & Safety.	90	Desktop			
No.3 Q 5	Management System Risk Management	Other – Major	There was no systematically policies or practices in place to risk assess their programs and potential business impacts on reputation risks and legal risk.	The company should establish policies and/or practices in place to risk assess their programs and	180	Follow Up			

			企业没有建立系统的政策或实践对其项目和潜在的业务影响进行声誉风险和法规风险方面的评估。	potential business impacts including business interruption risks, reputation risks and legal risk.					
No.4 Q 6	Management System Risk Management	Other – Minor	The Change Control Procedure of company did not consider the impact from changes on Ethics and Labor aspects, and the procedure was not implemented. 企业的变更管理流程没有考虑变更对道德和劳工方面的影响,并且没有按照程序执行。	The Change Control Procedure should consider the impact from changes on HSE, Ethis and Labor aspects.	90	Desktop			
No. 5 Q 11	Management System Continual Improvement	Other – Minor	The company did not have formal processes and procedures to assess the effectiveness of its labor, ethics and HSE practices, to identify and implement corrective actions and/or recommendations, and to track corrective actions. No regular internal audit, corrective action plan tracking or management review conducted. 企业没有在劳工、道德规范和HSE（健康、安全和环境）方面建立有效性评估流程和程序，以识别和实施纠正措施或建议措施，并跟踪纠正措施，没有执行定期的内审，纠正措施跟踪，管理评审。	The company should conduct regular internal audit, corrective action plan tracking or management review to to assess the effectiveness of its labor, ethics and HSE practices, to identify and implement corrective actions and/or recommendations, and to track corrective actions.	180	Desktop			
No.6 Q 12	Ethics Business Integrity and Fair Competition	Other – Minor	The current ethics policies did not cover fair competition, investigation of employee concerns. 企业现有的道德伦理政策没有包含公平竞争，针对员工关注问题的调查机制。	The company should improve the current ethics policy to cover fair competition, investigation of employee concerns.	90	Desktop			
No.7 Q 16	Labor	Other – Minor	The company did not have a policy regarding Prohibition of	The company should improve the current	90	Desktop			

	General		<p>child labor, freely chosen employment, freedom of association, non-discrimination, Grievance mechanism, Whistle blower reporting and anti-retaliation policy, Anti-Human Trafficking, Freedom of Movement, etc.</p> <p>企业未能建立书面的禁止使用童工,自由受雇,自由结社,禁止歧视,意见申述管理机制,秘密举报及反报复制度,禁止贩卖人口及行动自由的管理政策。</p>	<p>labor management system to include all required policies, regarding Prohibition of child labor, freely chosen employment, freedom of association, non-discrimination, Grievance mechanism, Whistle blower reporting and anti-retaliation policy, Anti-Human Trafficking, Freedom of Movement, etc.</p>					
No. 8 Q 17	Labor Freely Chosen Labor	Other – Minor	<p>The company did not perform a risk assessment to determine if there are areas of their business at risk for forced, bonded, or involuntary prison labor.</p> <p>企业未能进行风险评估,以确认其业务是否存在任意形式的强迫劳动。</p>	<p>The company should perform a risk assessment to determine if there are areas of their business at risk for forced, bonded, or involuntary prison labor.</p>	90	Desktop			
No. 9 Q 21	Labor Child Labor and Young Workers	Other – Minor	<p>The company did not establish any employment procedure regarding the policy of "Prohibition of child labor" and "Child labor remediation".</p> <p>企业未能建立禁止使用童工的程序及童工拯救程序。</p>	<p>The company should establish any employment procedure regarding the policy of "Prohibition of child labor" and "Child labor remediation" in case any child labor detected.</p>	90	Desktop			
No. 10 Q 23	Labor Non-Discrimination and Fair Treatment	Other – Minor	<p>The company did not establish any policy regarding anti-discrimination. And related non-discrimination training could not be provided to the employees.</p> <p>企业未能建立禁止歧视的政策,故相关培训未能提供。</p>	<p>The company should establish policy regarding anti-discrimination and communicate it with the employees.</p>	90	Desktop			
No. 11-1 Q 24	Labor	Other – Major	<p>Based on the company policy, the overtime work on weekday</p>	<p>The company should ensure employees are</p>	180	Follow Up			

			<p>will be just exchanged for deferred rest instead of be paid for overtime wage. For example, 1 out of 10 sampled employees have worked overtime on weekdays for 130 hours since January 2019, but 57 out of 130 hours have been exchanged for deferred rest, the other 73 hours overtime have been not paid. Besides, based on company policy, the overtime worked will be calculated by hour, overtime less than 1 hour will not be accounted or paid.</p> <p>Law reference: Article 44 of the Labor Law of the PRC</p> <p>根据企业政策，工作日的加班仅用来调休而非支付加班费，例如抽样的10名员工，其中一名自2019年1月以来工作日加班累计130小时，其中仅有57小时已换取调休，剩余的73小时加班没有支付加班费。另外企业规定，加班以1小时起算，不足1小时不记为加班不支付加班费。</p> <p>参考法规：《中华人民共和国劳动法》第44条</p>	properly compensated for all overtime worked.					
No. 11-2 Q 24	Labor Wages, Benefits, and Working Hours	Other – Minor	<p>Based on 10 sampled workers' time records of May 2019, August 2019 and November 2019, 1 out of 10 sampled workers exceeded the daily overtime working hours limited of 3 hours per day in November 2019, August 2019 and May 2019 respectively, the maximum daily overtime working hours were 5 hours per day in August 2019; none out of 10 sampled workers exceeded the monthly overtime working hours limited of 36 hours per month in November 2019, 3 out of 10 sampled workers exceeded the monthly overtime working hours limited of</p>	The company should ensure that employee overtime hours do not exceed the statutory limits.	180	Desktop			

			<p>36 hours per month in August 2019, 3 out of 10 sampled workers exceeded monthly overtime working hours limited of 36 hours per month in May 2019, the maximum monthly overtime hours are 99 hours per month in August 2019.</p> <p>Law reference: Article 41 of the Labor Law of the PRC</p> <p>根据 10 个抽样工人 2019 年 11, 8, 5 月考勤记录, 3 个月各有 1 名抽样工人日加班超过 3 小时, 最大为 2019 年 8 月的每天加班 5 小时; 2019 年 11, 8, 5 月分别有 0/3/3 名抽样工人月加班超过 36 小时, 最大为 2019 年 8 月的每月加班 99 小时.</p> <p>参考法规: 《中华人民共和国劳动法》第 41 条</p>					
No. 12 Q 25	Labor Wages, Benefits, and Working Hours	Other – Minor	<p>Based on 10 sampled workers' time records of May 2019, August 2019 and November 2019, 2 out of 10 sampled workers worked consecutively for 9-14 days in November 2019, 3 out of 10 sampled workers worked consecutively for 7-10 days in August 2019, 3 out of 10 sampled workers worked consecutively for 9-19 days in May 2019.</p> <p>Law reference: Article 38 of the Labor Law of the PRC</p> <p>根据 10 个抽样工人 2019 年 5, 8, 11 月考勤记录, 2 名抽样工人在 2019 年 11 月连续上班 9-14 天, 3 名抽样工人在 2019 年 8 月连续上班 7-10 天, 3 名抽样工人在 2019 年 11 月连续上班 9-19 天。</p> <p>参考法规: 《中华人民共和国劳动法》第 38 条</p>	The company should ensure that employees have at least one day off every seven consecutive days.	180	Desktop		

No. 13 Q 26	Labor Wages, Benefits, and Working Hours	Other – Minor	Based on company employee manual, it was noted that employees would be fined if they violated factory's rules, such as fine RMB 50 for swipping attendance card for others, fine RMB 50 once for being late for work more than three times, and etc. But no actual case happened during the reviewing of samples. Law reference: Article 50 of the Labor Law of the PRC 企业员工手册有罚款规定, 比如他人刷卡考勤罚款 50 元, 迟到 3 次以上每次罚款 50 元等。但是抽样员工没有发现此类扣款。 参考法规: 《中华人民共和国劳动法》第 50 条	The company should abolish the Monetary fine policy.	90	Desktop			
No. 14 Q 27	Labor Wages, Benefits, and Working Hours	Other – Minor	The wages due were paid to employees on next pay day (within one month). Law reference: Article 7 of Regulations of the Shanghai city on the wage payment to employees 离职员工的工资在下一个发薪日发放 (1 个月内)。 参考法规: 《上海市企业工资支付办法》第 7 条	The company should ensure that resigned / terminated employees are properly compensated per legal requirement.	180	Desktop			
No.15 Q 30	Labor Logistics Subcontractors	Other – Minor	The company did not establish process for managing human rights risks at third party logistics (3PL) providers, including not assess 3PL's process on monitoring subcontractors. 企业未建立管理第三方物流 (3PL) 供应商的人权风险的机制,也未对第三方物理公司是否监管其分包商进行核实。	The company should establish process for managing human rights risks at third party logistics (3PL) providers.	180	Desktop			
No.16 Q36	Environment Protection	Other Major	1) Site 1 operated on Aug 2019 after renovation, but the company did not receive the environmental inspection and	1)The company should monitor the air emission and wastewater, pass the environment	180 days	Desktop			

	Environmental Authorizations		<p>final approval, the company did not monitor the wastewater and air emission yet and did not receive the full pollutant discharge permit.</p> <p>2) Site 2 renovation project was on going, the EIA was ongoing by 3rd party, but not completed yet by now.</p> <p>1) 一厂在 2019 年 8 月完成改造, 但还没有取得环境的最后验收和批复, 没有检测空气排放和废水, 没有取得排污许可证。</p> <p>2) 二厂的改造项目正在进行, 但还没有完成环评</p>	<p>inspection from authority for site 1 and receive the pollutant discharge permit.</p> <p>2)The company should complete the EIA for site 2 asap.</p>					
No.17 Q39	Environment Protection Waste and Emission	Other Minor	<p>The company did not establish the wastewater treatment procedure to manage the wastewater.</p> <p>企业没有建立废水运行控制程序</p>	<p>The company should establish the wastewater treatment procedure to manage the wastewater.</p>	60 days	Desktop			
No.18 Q40	Environment Protection Waste and Emission	Other Minor	<p>There was no air emission monitoring outlet for 5 new exhaust fans at roof.</p> <p>在屋顶的 5 台新的排风机没有安装排风检测口。</p>	<p>The company should install the air emission monitoring outlet for 5 new exhaust fans at roof.</p>	180 days	Follow up visit			
No.19 Q45	Environment Protection Spill and releases	Other Minor	<p>1)Total 6 barrels of waste chemicals (20Litre each) were stored in 5cm high container. The spill containment system (about 2 Litre containment) cannot meet the requirement</p> <p>2)There was no spill kit at Mass Spectrometry room and hazardous chemical storage room.</p> <p>1) 6 桶废液(20 升)装在只有 5 厘米高的防泄漏容器中, 防泄漏容积 (估计只有 2 升) 不能满足要求</p> <p>2) 在质谱间和危险化学品存放间没有防泄漏站</p>	<p>1)The company should expand the containment to meet the requirement.</p> <p>2) The company should set the spill kit at Mass Spectrometry room and hazardous chemical storage room.</p>	60 days	Follow up visit			

No.20 Q48	Health & safety General	Other Minor	The company had not the detail action plan and track the performance trend for the target. 企业没有详细的行动计划来跟进绩效趋势实现目标	The company should setup the detail action plan and track the performance trend for the target.	60 days	Desktop			
No.21 Q65	Health and Safety Occupational Health and Industrial Hygiene	Other Minor	There was no forced ventilation system for 5 flammable cabinets at room 135, chemical storage area. 化学品存放间的 5 个易燃品柜没有安装排风装置	The company should install the forced ventilation system for 5 flammable cabinets at room 135, chemical storage area.	60 days	Follow up visit			
No.22 Q68	Health and Safety Occupational Health and Industrial Hygiene	Other Major	The company did not perform the occupational health medical monitoring to new employee and health surveillance monitoring to present employee, including post job employee in 2019. 企业在 2019 年没有为所有接触化学品危害因素的员工做职业健康体检, 包括新员工和离职员工。	The company should perform the occupational health monitoring to employee who exposed to hazardous chemicals annually.					
No.23 Q70	Health and Safety Occupational Health and Industrial Hygiene	Other Major	1) The Nitrogen gas was widely used at the Mass Spectrometry room. But the company did not assess the risk of N2 leakage, take action and establish the n emergency response plan. 2) The company did not perform the site exposure monitoring for chemicals at lab for site 1. 3) The company did not receive the final inspection and acceptance for occupational health for site 1. 1)在质谱间使用较多的氮气, 企业没有检测氮气是否泄漏和应急措施 2)企业没有对化学品暴露的现场做危害因素检测 3)企业没有对新项目做职业危害评价的验收	1)The company should assess the risk of N2 leakage risk, take action and establish emergency response plan. 2)The company should perform the site exposure monitoring for chemicals at lab for site 1. 3)The company should pass the final inspection and acceptance for occupational health for site 1.	180 days	Follow up visit			
No.24 Q71	Health and Safety	Other Minor	The company did not inform employees of the results of exposure evaluations and	The company should inform employees of the results of exposure	180 days	Desktop			

	Occupational Health and Industrial Hygiene		monitoring results. No occupational hazard notification was the labor contract. 企业没有告知现场职业健康危害因素暴露评估和检测结果, 在合同中也没有通知员工。	evaluations and monitoring results and occupational hazard notification in the labor contract.					
No.25 Q85	Health and Safety Emergency Preparedness and Response	Other Minor	The site 1 was put into use in Aug 2019 after renovation, but the company did not inspect the extinguisher regularly. 企业在 2019 年 8 月改造完成, 还没有对灭火器进行常规检查	The company should inspect the extinguishers regularly.	30 days	Follow up visit			
No.26 Q86	Health and Safety Emergency Preparedness and Response	Other Minor	There was no fire alarm handling process at the company. The FM200 (HFC-227ea) fire system at archives room was on manual status. 企业没有建立火灾报警处理程序。档案室的气体灭火系统处于手动状态。	The company should make sure the FM200 system on normal operation.	30 days	Follow up visit			
No.27 Q88	Health and Safety Emergency Preparedness and Response	Other Major	There was no evacuation map posted at the labs and office area. 实验室和办公室没有设置应急逃生图	The company should post the evacuation map at each area.	60 days	Follow up visit			
No.28 Q92	Health and Safety Hazard information	Other Minor	1) There was no SDSs at chemical storage room (room 135) 2) There was no GHS labelling for compound chemicals at preparation room. 1) 在化学品存放间没有化学品安全数据表 2) 在配制的化学品没有 GHS 标识	1)The company should post the SDSs for the chemical storage room. 2)The company should post the GHS label for the compound chemicals.	60 days	Follow up visit			

Note:

Critical Observations: Are high or very high risk observations that *require immediate action* to protect human life, the health of employees or the environment; may result in loss of license to operate, damage to reputation. *A critical observation requires immediate corrective action by the supplier.*

Other Observations: Are observations that require corrective actions that are managed against a timeline commitment by the audited site.

PSCI Supplier Corrective Action Plan Report (CAPR)

Confirmation

Must be signed by both parties and returned to PSCI@bsr.org within 30 days of on-site audit

Please sign this document confirming that the above findings have been discussed with and understood by you: (site management)

Site Representative Signature:

Name: [Redacted]

Title: Director

Date: 06 December 2019

Auditor Signature:

Name: [Redacted]

Title: Auditors

Date: 06 December 2019

Please indicate below if you, the site management, dispute any of the findings

I dispute the following numbered Findings:

None

Signed:

Title: Director

Date: 06 December 2019

Site Comments:

None